Attachment 10

Battelle IRB Approval letter

Battelle Memorial Institute
Federalwide Assurance FWA00004696; IRB No. IRB00000284
Battelle Institutional Review Board

INSTITUTIONAL REVIEW BOARD NOTICE – FULL APPROVAL WITH CONDITIONS

Principal Investigator/Project Manager : April Greek

Proposal/Project Title : Case Investigation of Cervical Cancer (CICC) Study

Client/Funding Agency : HHS Centers for Disease Control and Prevention

IRB No. : IRB 0617-100069348 Rev 0.0

Date of Submission to IRB : 1 June 2016

Proposal No. : OPP200998/ CON00023780

Project No. : 100069348

Subcontract to Battelle from N/A (if applicable)

Subcontract from Battelle to N/A (if applicable)

Level of Review

☒ Expedited Approval. Minimal Risk to Human Subjects per 45 CFR 46.110 (b)(1):

- Category 7 - Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Subject to HIPAA regulations at 45 CFR 164. Participants will voluntarily provide their AUTHORIZATION to contact participants' healthcare provider(s). Under HIPAA authorization, healthcare providers will send applicable PHI to designated State Cancer Registries. Each State Cancer Registry will prepare and provide a Limited Use Dataset to Battelle under the terms of a Data Use Agreement. Battelle will not be in possession of participants' Protected Health Information (PHI) at any point in this research.

Type of Approval – IRB FULL APPROVAL with CONDITIONS

All phases of research may proceed subject to the following Condition:

The Principal Investigator may NOT receive any human subject data FROM a participating State Cancer Registry WITHOUT the Battelle IRB's verification/acknowledgement that a fully executed Data Use Agreement has been established.

Upon the Battelle IRB's verification/acknowledgement of same, the research study may proceed without restriction.

See IRB Requirements and Restrictions (Page 2 of 3).

This study continues approval to 3 March 2017.

Rosalie Meyer Rader — 6/1/2016

Signature — Date

Co-Chair, Battelle Institutional Review Board

Rosalie Meyer Rader

Print or Type Name

Battelle
The Business of Innovation

Requirements and Restrictions

IRB Requirements:

- The IRB shall possess an appropriate Translation Certificate for each study document translated into a language other than English.
- Per 45 CFR 46.109(e), the IRB has the authority to observe or to have a third party observe the consent process and the research.
- Per 45 CFR 46.113, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Continuing Review/Approval. Federal regulations require that human subjects research protocols maintain IRB approval for the entire duration of the research study, including data analysis and report writing. If this project will continue beyond 3 March 2017, the final day of approval, apply for continuing approval of IRB 0617-100069348 Rev 0.0.

Approval for Amendments. Seek the IRB's approval for any proposed amendments/ revisions to the protocol, including changes to study documents and recruiting materials. Federal regulations require that the IRB re-review and re-approve human subjects research prior to implementing any proposed amendments or revisions. Complete and submit an application for amendment to the IRB manager.

Reporting. The following events must always be reported to the IRB:

- Unforeseen events (within four (4) hours of discovery). See definition of "unforeseen event" on page 3 of 3.
- Protocol violations that
  - Placed a human subject at risk, or
  - Were caused by the action or inaction of a researcher
- New or changed risks to human subjects, including new findings
- Failure to follow regulations or IRB requirements
- Unresolved complaint by a human subject
- Audit, inspection, or inquiry by a federal agency
- Breach of confidentiality
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a human subject
- Incarceration of a human subject.

Documentation Control Requirements. Study documents and records, e.g., informed consent documents and data collection instruments, must be maintained in accordance with established confidentiality measures. Federal regulations require that all documents and records be retained for at least three (3) years after a study is formally closed. Battelle policy or client requirements may require a longer retention.

Definitions

Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal regulations at 45 CFR 46.110 permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Only the IRB can determine if a proposed research activity meets the requirements for expedited review.

Adverse Event - An event or incident not previously known or not anticipated to result from:

- The interactions or interventions used in the research;
- The collection of privately identifiable information under the research;
- An underlying disease, disorder or condition of a human subject, and/or,
- Other circumstances unrelated to the research or any underlying disease, disorder or condition of the subject.

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Depending upon applicable regulations, "minimal risk" may be defined differently for minors and other vulnerable populations.

Nonconformance - A determination that some aspect of a research study has not been performed in accordance with applicable laws and regulations, ethical standards, Battelle policies, IRB requirements, or contractual obligations.

Unforeseen Event - - A Battelle-coined term that has no regulatory equivalent, but that may summarize one or more of the following terms: (1) adverse event; (2) unanticipated problem involving subjects or others; or (3) non-conformance. Unforeseen Events must be reported to an IRB via an established reporting process.

Unanticipated Problem Involving Subjects or Others - An event in a human research study that is not expected given the nature of the research procedures and the subject population being studied, and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.